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GUIDELINE ON THE STANDARD OPERATING METHOD PRINCIPLES OF ETHICS COMMITTEES FOR COSMETIC CLINICAL TRIALS VERSION 1.0 KÜD-KLVZ-45

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Objective

ARTICLE 1- (1) This Guideline has been prepared pursuant to the requirements of the Regulation on Efficacy and Safety Studies and Clinical Trials of Cosmetic Products or Raw Materials in order to provide guidance on the establishment and operating methods of Ethics Committees for Cosmetic Clinical Trials.

Scope

ARTICLE 2- (1) This Guideline has been prepared for Ethics Committees for Cosmetic Clinical Trials.

Legal Basis

ARTICLE 3- (1) This Guideline has been prepared on the basis of the Regulation on Efficacy and Safety Studies and Clinical Trials of Cosmetic Products or Raw Materials, which was published in the Official Gazette No. 29481 dated 20/09/2015 and entered into force.

Definitions

ARTICLE 4- (1) In this Guideline; a) Study or research protocol: the document that describes in detail the objective, methodology, statistical methods to be applied, and arrangements of the efficacy studies, safety studies, or clinical trials of cosmetic products or raw materials, b) Sponsor: the person, institution, or organization responsible for the initiation, conduct, or financing of the efficacy studies, safety studies, or clinical trials of cosmetic products or raw materials, c) Ethics Committee for Cosmetic Clinical Trials: the independent committees to be established or approved by the Agency for the purpose of providing scientific and ethical opinions on the study or research protocol, the suitability of the investigators, the adequacy of the facilities where the study or research will be conducted, the methods and documents to be used in informing the volunteers, the consents to be obtained from the volunteers, and other matters related to the studies or research, in order to ensure the protection of the rights, safety in terms of health, and well-being of the volunteers who will participate in the study or research to be conducted with cosmetic products or raw materials, and to ensure that the study or research is conducted and followed up in accordance with the relevant legislation, ç) Agency: the Turkish Medicines and Medical Devices Agency (TİTCK), d) Responsible investigator: the person who has completed education at the level required by the study or research in the field related to the subject of the study or research, and who is responsible for the conduct of the study or research, e) Contract research organization (CRO): the independent organization to which the sponsor has transferred, in whole or in part, the duties and authorities related to the efficacy studies, safety studies, or clinical trials of cosmetic products or raw materials by means of a written contract,

shall mean.

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Method to be followed in establishing ethics committees

ARTICLE 5- (1) The ethics committee is established within the framework of the legislation in such a way as to ensure that it reviews the study or research protocols applied for in accordance with their ethical and scientific aspects, and that its members are kept away from all prejudices and influences that may affect the impartiality of their duties. (2) Applications for the establishment of an ethics committee shall be made to the Agency with the documents published on the Agency's website. (3) Ethics committees are established at universities upon the proposal of the rector, in Public Hospital Unions upon the proposal of the secretary general, and at Gülhane Military Medical Academy upon the proposal of the dean, with the approval of the Agency, and commence their activities as of this approval date. (4) Ethics committees are composed of at least seven and at most fifteen members, provided that at least one member is a person who is not a healthcare professional and one is a legal professional, and the majority of the members are healthcare professionals educated at the doctoral or medical specialization level. (5) Ethics committees are constituted in the form of an Ethics Committee for Cosmetic Clinical Trials. (6) The Ethics Committee for Cosmetic Clinical Trials shall include members with the qualifications specified below: a) A pharmacist who has obtained a doctoral degree in the field of pharmaceutical technology, preferably with studies in the field of cosmetology, b) A pharmacist or physician who has obtained a doctoral degree in the field of pharmaceutical toxicology, c) A pharmacist who has obtained a doctoral degree in the field of pharmacognosy or pharmaceutical botany, ç) A pharmacist who has obtained a doctoral degree in the field of pharmaceutical chemistry, d) A pharmacist who has obtained a doctoral degree in the field of pharmacology or a physician who has completed specialization, e) A physician who has completed specialization in the field of dermatology and venereal diseases, f) A dentist who has completed specialization in the field of periodontology, g) A legal professional, ğ) A person who is not a healthcare professional, h) If available, a person who has completed a doctorate or specialization in the field of medical ethics (deontology), ı) In cases where an expert opinion is required; persons who have obtained a specialization or doctoral degree in the required field. (7) It is mandatory for the Ethics Committee for Cosmetic Clinical Trials to include members with the qualifications specified in subitems (a), (b), (c), (ç), (e), (g), and (ğ) of paragraph 6 above. (8) The ethics committee provides timely, comprehensive, and independent review of the ethical and scientific characteristics of the studies or research submitted to it.

Conditions for the appointment of ethics committee members and matters to be complied with

ARTICLE 6- (1) The term of office of the ethics committee members is two years. (2) Memberships are renewed every two years in the manner specified in the third paragraph of Article 5. (3) The membership of any member who, without a valid excuse, fails to attend three consecutive meetings or five non-consecutive meetings during their term of office shall automatically terminate. In place of a member whose term of office has expired or whose membership has terminated, a new member possessing the same qualifications shall be appointed in the manner specified in the third paragraph of Article 5. (4) In the event that the duties of any of the members who are mandatorily required to be present at a minimum pursuant to the legislation terminate, the ethics committee may not take any decision until a new member of the same qualification is appointed in the manner specified in the third paragraph of Article 5 as of the date on which the duties terminated, and such appointment is approved by the Agency. (5) An ethics committee member may not serve as a member in more than one ethics committee. (6) At least three of the ethics committee members must be from outside the institution where the ethics committee secretariat is located. The term "institution" as used here encompasses, in universities, all institutions and organizations affiliated to the Rectorate; in Public Hospitals Unions, all institutions and organizations belonging to the Union to which the hospital is affiliated; and in Gülhane Military Medical Academy, all institutions and organizations affiliated to the Academy. (7) Senior executives of the place where the work or research is conducted (Rector, Vice-Rector, Dean,

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Vice-Dean, Secretary General of the Public Hospitals Union, Chief Physician, Hospital Manager, etc.) may not serve on ethics committees. (8) Ethics committee membership terminates only in the following cases: a) Completion of the term of office, b) Written statement of resignation, c) Determination or declaration by the member that he/she will be unable to attend ethics committee meetings for a continuous period exceeding six months due to reasons such as an assignment abroad or a health problem, ç) Failure to attend three consecutive meetings or five non-consecutive meetings without a valid excuse during the term of membership, d) Determination of a violation of ethical rules. (9) The document indicating the date on which the membership of a member whose ethics committee membership has terminated ended must be submitted to the Agency. (10) Ethics committee members may serve for more than one term if deemed appropriate. (11) Ethics committee members must exercise due diligence regarding the issue of conflict of interest. (12) Ethics committee members are obliged to comply with the principle of confidentiality with respect to all information reaching them, and they commence their duties upon signing the confidentiality agreement and declaration of commitment document to be prepared and published on the website by the Agency; the said documents shall be renewed on the same date each year and submitted to the Agency.

Working procedures and principles of ethics committees

ARTICLE 7- (1) Ethics committees are independent in evaluating work or research applications scientifically and ethically and in granting approval. (2) Ethics committee members convene with a two-thirds majority of the full membership and take decisions by an absolute majority of the full membership. (3) The members, following the establishment of the committee with the approval of the Agency, convene within fifteen days at the latest and elect, by secret ballot, a chair and a deputy chair from among themselves. Furthermore, they elect a member who will evaluate cases for which, pursuant to the legislation, mere notification is sufficient, and notify the Agency thereof. (4) In the absence of the ethics committee chair, the deputy chair acts as the proxy. The ethics committee chair or acting chair conducts and closes the meeting. (5) Ethics committees obtain, when necessary, the written opinion of experts from the relevant primary or secondary field and invite such persons to the meeting as advisors. These persons attend the meeting after signing the confidentiality agreement and declaration of commitment document to be published by the Agency on its website. (6) The opinions of the advisors invited to the meeting are obtained and evaluated. (7) If there is any change in the work or research protocol or the informed consent form (ICF), it is submitted to the approval of the ethics committee after obtaining the opinion of the relevant advisor. (8) An ethics committee member who has a relationship with, or a duty in, the work or research under review may not participate in the discussions and voting of the ethics committee regarding that work or research, and may not sign the ethics committee decision.

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Ethics committee secretariat

ARTICLE 8- (1) After the ethics committees commence their activities in the manner specified in the third paragraph of Article 5, they conduct their correspondence through their own secretariat; with the Agency and the sponsor, the contract research organization to be assigned by the sponsor, or the principal investigator. (2) Tasks such as receiving the applications submitted to the ethics committee, informing the sponsor, the contract research organization to be assigned by the sponsor, or the principal investigator, archiving the documents, conducting the necessary correspondence, organizing the meetings and similar duties are carried out by the ethics committee secretariat. (3) The personnel to serve in the ethics committee secretariat (at least two persons) are assigned by the institution/organization in which the ethics committee is established. These persons are obliged to comply with the principle of confidentiality with respect to all information reaching them; they commence their duties upon signing the confidentiality agreement and declaration of commitment document to be published by the Agency on its website, and the said documents shall be renewed on the same date each year and submitted to the Agency.

Duties and powers of ethics committees

ARTICLE 9- (1) The ethics committee is required to comply with and fulfil the requirements set out in the Regulation on Clinical Trials and Safety and Efficacy Studies of Cosmetic Products or Ingredients and related guidelines and documents. (2) When forming an opinion on an application for a study or research, ethics committees shall evaluate: a) the analysis of the expected benefits, harms and risks of the study or research, b) whether the study or research is based on clinical data and a new hypothesis, c) the suitability of the study or research, ç) in the case of studies or research to be conducted on humans for the first time, the necessity that they have first been carried out in a non-human experimental setting, d) whether, based on the data obtained from experiments conducted in a non-human experimental setting, the study or research has reached a maturity sufficient to be conducted on humans for the purpose of attaining the intended objective, and whether this necessitates its conduct on humans, e) the study or research protocol, f) whether the study or research is being conducted with substances prohibited from use as cosmetic products or ingredients, g) in the case of substances with restricted use as cosmetic products or ingredients, that no study or research is being conducted with substances intended for use outside the specified limits, ğ) the written information provided in connection with the study or research, and the method followed for the purpose of obtaining the informed consent of volunteers, h) whether the application contains information demonstrating that measures have been taken against undesired/serious undesired effects, ı) in the event of health problems arising from the study or research, or the occurrence of an undesired and/or serious undesired effect, the liability of the sponsor, the contract research organisation assigned by the sponsor or the principal investigator, and the scope of the insurance certificate or policy taken out for volunteers, i) the suitability of the entire team involved in the study or research, j) documents related to the safety of the cosmetic products or ingredients that are the subject of the study or research, k) the safety assessment report, l) the arrangements concerning the enrollment of volunteers in the study or research,

m) the budget relating to the compensation arrangements deemed appropriate for investigators and volunteers, and, where any agreement has been concluded between the sponsor and the site where the study or research will be conducted, the relevant sections of that agreement. (3) The ethics committee notifies the applicant of its opinion within at most fifteen working days from the date of application. (4) Where additional information and explanations are required during the review process of the ethics committee, all necessary requests are conveyed to the applicant in a single instance. No further request shall be made of the applicant. The review process is suspended until the requested information and documents are submitted to the ethics committee. (5) The ethics committee may monitor any study or research it has approved, either

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with or without prior notice; in addition, the Agency may request the ethics committee to monitor a study or research. The ethics committee sends the monitoring report to the Agency within at most fifteen working days. These reports are evaluated by the Agency. (6) The ethics committee may request the Agency to order the termination of studies or research in which non-compliance is identified.

Application to the ethics committee and the method of processing the application

ARTICLE 10- (1) For the first application to be made to the ethics committee, where the ethics committee so requests, the application fee shall be paid in the manner specified by the institution/organisation in which the ethics committee is established, without exceeding the application fee determined and published on the website by the Agency; the original of the payment receipt and one copy thereof shall be attached to the application file. No application fee is requested for studies or research conducted for academic purposes (thesis, project, etc.). (2) The application is made by the sponsor, the contract research organisation assigned by the sponsor or the principal investigator, and the ethics committee secretariat conducts all correspondence with the sponsor of the application, the contract research organisation assigned by the sponsor or the principal investigator. Review method

ARTICLE 11- (1) The members of the ethics committee are required to convene in accordance with the meeting dates planned and announced in advance by the ethics committee secretariat. (2) The ethics committee may declare a holiday period of at most fifteen days within the year, provided that it is announced at least one month in advance. (3) Where necessary, the applicant or investigators are invited to the ethics committee meeting for the purpose of obtaining information about the application. (4) The current applications are taken up, including applications made at least three working days prior to the meeting date. Applications are taken up for evaluation in chronological order. However, applications that cannot be evaluated at the meeting shall be evaluated at the next agenda in the chronological order of application. (5) In its review, the ethics committee shall take into consideration the following points in addition to the matters specified in the legislation:

a) the adequacy of the information submitted and its capacity to respond to ethical questions arising during the study or research, b) the suitability of the protocol with respect to the objectives of the study or research, c) the completeness, adequacy and comprehensibility of the written and verbal information to be provided to volunteers and, where applicable, their legal representatives regarding the study or research, ç) measures to ensure the confidentiality and protection of personal data belonging to volunteers, d) where available, the payments specified in the study or research budget.

Decision-making method

ARTICLE 12- (1) The decision of the ethics committee is taken under the chairmanship of the ethics committee chair or deputy chair, after sufficient time is allotted for review and discussion, following the departure from the meeting of third parties in connection with the applications under review. (2) Where the ethics committee decision is taken by an absolute majority of the full membership, the members who did not take part in the decision sign their dissenting grounds during the meeting. (3) The members of the ethics committee write their name and surname, the exact title of the study or research, and the subject matter and their decision in a clear and comprehensible manner on the review form, sign it and date it. (4) The ethics committee decision is finalised with the signature of the chair or deputy chair.

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Method for communicating the decision

ARTICLE 13- (1) After the meeting at which the decision is issued, the decision must be communicated by the ethics committee secretariat to the Agency and the applicant by means of an official letter within no more than fifteen working days. (2) The applicant is responsible for communicating the decision to all sites in multicentre studies or research. (3) The ethics committee decision form must conform to the form published on the Agency's website, and the relevant fields of the form must be completed in full. (4) The certified-true copy approval of the ethics committee decision form is carried out by the ethics committee chair or deputy chair.

Documentation and archiving method

ARTICLE 14- (1) All documents and correspondence belonging to the ethics committee shall be dated, filed and archived. (2) Only the members and the secretariat of the ethics committee may access the documents of the ethics committee.

(3) The documents of the ethics committee to be filed and archived shall include the following: a) The establishment of the ethics committee and historical documents, b) Curricula vitae of all ethics committee members, c) Curricula vitae of the personnel serving in the secretariat of the ethics committee, ç) Signed confidentiality agreements and declarations of commitment, d) Announcements determined and published by the ethics committee, e) All information submitted by the applicant, f) All correspondence regarding the application, decision and follow-up conducted between the ethics committee members and the applicant or other relevant parties, g) The agenda of the ethics committee meetings, ğ) A copy of the ethics committee decision and all information sent to the applicant, h) All files, information, documents and materials submitted to the ethics committee during an inspection. (4) All archived files, including documents and their annexes, shall be retained for at least five years.

Entry into Force

ARTICLE 15- (1) This Guideline shall enter into force upon the approval of the President of the Agency.

Execution

ARTICLE 16- (1) The provisions of this Guideline shall be executed by the President of the Agency.

REVISION HISTORY Revision No Revision Date Justification and Explanations 1 15.11.2022 An update has been made regarding systemic requirements.

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